METHOD AND DEVICE FOR INSPECTING AND MONITORING THE SEAL INTEGRITY OF STERILE PACKAGES

The present invention relates to a device and method for inspecting and monitoring the seal integrity of sterile medical packages, and more particularly, to a device having an integral seal peel tester for collecting and correlating test data in order to maintain compliance to FDA's quality system regulations; the invention also relates to an external visual inspection unit for side lighting the seal area of the package for inspecting seal integrity

BACKGROUND OF THE INVENTION

A basic medical sealer requires four basic components to work properly: a solenoid or pneumatic piston, a jaw mechanism, a heating element, and a microprocessor. Referring to Figs. 1 and 3, the machine 10 of a basic medical sealer includes a solenoid 12 (Fig. 3) and a jaw mechanism 13 comprised of an upper jaw 14 and a lower jaw 16. Solenoid or pneumatic piston 12 engages the jaw mechanism to pull the upper jaw 14 down onto lower jaw 16 in order to apply the necessary pressure to the flexible package or pouch. Solenoid 12 has a pre-defined pressure that is fine-tunable by a control knob 18 on the upper jaw assembly.

As shown in Fig. 3, a heating element 20 flash heats to the required temperature to melt the packaging material. Heating element 20 maintains the temperature for a specific time to create a bond. Pieces of Teflon, Sarcon, and glass cloth are disposed on either side of heating element 20 and prevent the packaging materials from sticking to the upper and lower jaws. The heating element is controlled by a microprocessor 22, shown in Fig. 2, with a thermocouple interface to assure the accuracy of the temperature. Microprocessor 22 also controls the cooling time during which the jaws stay closed before the material can be removed from the machine.

Packages sealed by medical sealers must meet government standards; therefore, the seal integrity of packages must be routinely tested during production. There are different tests for inspecting seal integrity, the most common being peel testing and visual testing. Peel testing is the most common way to determine seal strength utilizing destructive methodology. These test modalities are used when developing the Design of Experiments for the validation processes. The visual process is used most often as an in-process system of seal inspection as it is non-destructive. Peel testing measures the strength of seal in pounds while visual testing analyzes seal integrity for pleating, cracking, bubbling, etc. Basic medical sealers used in the art today do not include a mechanism for thorough inspection of seal integrity of the package being sealed. Currently, when a medical packager seals a pouch using a medical sealer, he or she must occasionally pull a pouch out of production to test the seal. Testing the seal usually involves taking it to a lab where the material is cut into a one-inch strip and pulling the material apart using, for example, an industrial ASTM F-88 seal strength test to determine the integrity of the seal. Alternatively, devices such as those disclosed in U.S. Patent Numbers 5,515,159 to Sikes, 6,097,427 to Dey et al., and 5,732,529 to Dey et al. are used, wherein the medical packager removes the package from production after it has been sealed and inspects the package with a light and a video camera.

SUMMARY OF INVENTION

A system for inspecting seal integrity of a sealed package is disclosed herein, including a side lighted visual inspection system and medical packaging device having an integral peel testing system. The visual inspection system comprises a housing, a lens removably attached to the housing, a slit within the housing, and a light source; wherein a seal of a package is placed within

the slit, the light source casts light from a side angle onto the seal, and the light enhances topography of said sealed portion of said package visible through the lens. The medical packaging device comprises the integral peel tester integral, a microprocessor coordinating with the peel tester, and a cutting mechanism; wherein, the medical packaging device prompts an operator to test a sample of sealed packages, a sample is removed from said medical packaging device, cut to an appropriate size using said cutting mechanism, and inserted into the peel tester, whereby the peel tester collects seal integrity data and shares the data with the microprocessor, which in turn analyzes the data in correlation to set standards.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic view of a basic medical packaging device.

Figure 2 is a front view of a medical packaging device microprocessor.

Figure 3 is an exploded view of a basic medical packing device.

Figure 4 is a schematic view of a visual inspection unit.

Figure 5 is a schematic view of a visual inspection unit with the lens removed.

Figure 6 is a back view of the visual inspection unit.

Figure 7 is a front, center cross-sectional view of the visual inspection unit.

Figure 8 is a side view of the visual inspection unit.

Figure 9 is a side view of the lens of the present invention.

Figure 10 is a schematic view of an embodiment of the medical packaging device of the present invention.

Figure 11 is a schematic view of an embodiment of the medical packaging device of the present invention.

DESCRIPTION OF THE INVENTION

The present invention provides systems for thoroughly inspecting seal integrity of sealed packages by peel testing and visual testing. The present invention includes an external visual inspection unit (VIU) for side lighting the seal area of a flexible pouch material, specifically that material used for sterile products, in order to enhance the topography of the seal area to reveal possible breaches in the seal integrity.

Referring to Figs. 4-8, visual inspection unit 30 includes a magnification lens 40 which preferably has a 3X magnification to enhance visual acuity during the inspection process. While 3X magnification is most preferred for this invention, weaker and stronger magnifications are feasible. Opening 32 within VIU 30 removably receives lens 40 while slit 34 within VIU 30 receives the sealed area of flexible material 36, as shown in Fig 8. On/off switch 38 and a contrast control knob 39 control the functions of VIU 30.

As shown in Figure 8, VIU 30 also includes a five LED high intensity light source 42, which illuminates across the package material thereby invoking shadows on the seal area, and a strip of glass 44 under which the package material is moved. Side lighting the seal area of the flexible pouch material in this manner greatly exaggerates irregularities such as folds, cracks, and bubbles in the material, and utilizing the side lighting approach in concert with the magnification provides superior visual inspection adjunct to total sterile packaging inspection.

Referring to Figs. 9-11, the present invention also includes medical packaging device (MP) 50 having an integral seal integrity peel tester 54, which can produce, for example, a 450mm seal length and a 10mm seal width. Hence, the device can be described as a MP-450-10 device. The MP 50 can function as a standard medical pouch sealer whereas heated jaws close together to heat up the sterile flexible pouch substrate and bond the material through a heating

and cooling cycle. The microprocessor 52 of MP 50 and the seal peel tester 54 correlate data with each other.

MP 50 will prompt the MP operator when it is time to perform a seal strength test. These test times are programmed into MP 50 such that, for example, after every five thousand seals MP 50 prompts the user into a test mode. When prompted, the operator removes a package from MP 50 and cuts a sample from the package using cutting bar 56 and clamps the sample into the peel tester 54, preferably using a vice and a thin film grip. The size is any size pre-determined to be suitable for insertion into the peel tester, preferably one inch. The sample is then pulled apart on a motorized stand at a rate of between eight to twelve inches per minute. As the peel tester 54 pulls the material apart, it gathers and records data that is extrapolated. Once the sample is pulled through the entire width of the seal, the operator would stop the MP 50 and gather the data. The data is preferably extrapolated by utilizing an x y histogram that shows that the seal was compliant by holding over one pound of pull over the length of the study. However, an extrapolation process can be used. This information can be sent to a storage device such as a computer for archiving and/or printing. After the operator has pulled apart a sufficient number of samples, for example five pouches, the MP 50 records the seal strength data, and if up to standard, allows the operator to continue on with the sealing function. Having the peel tester 54 integrated with the MP 50 allows the operator to perform the needed peel strength analysis at the MP 50, thereby increasing the efficiency of the seal package production process.

MP 50 also includes an off platen multi-spectrum seal inspection light 60 disposed in the lower jaw assembly which acts as an in-process optical sensing device that inspects seal integrity at the seal platen during the machine's standard production operation. If a breach in a seal is recognized by optical sensor 60, MP 50 will stop and sound an alarm or display an error code,

which will effectively reject the seal and prompt further inspection of the machine's operation.

As shown in Fig. 12, MP 50 can also include a palm or hand held type of computer that allows an operator to grab real time data, for example, dwell time, pressure, temperature, and download the same from the device. The palm or hand held computer 70 fits within an interface dock 72 and is configured with software that would aid in the management of preventative maintenance schedules and would allow operators to print a performance record in order to enhance compliance with various government regulations, i.e., the FDA's quality system regulations and/or ISO's requirements under 11607. In another embodiment, software could also correlate seal and test processes wherein information from the sealing process can be tied with the testing process.

The device can also have a modem that would allow the user to remotely calibrate the device. Presently, medical packaging devices must be sent to a lab for calibration. Oftentimes, the machines are damaged during the shipping process. By incorporating a modem, an operator would merely have to press a calibration button and the modem would dial into the designated computer. The device would then be prompted to go through a series of calibration performance exercises and the adjustments would be made remotely. After the operator logs off, a certificate of calibration could be sent via, for example, electronic mail.

Moreover, the device can include a sensor or sensors within MP 50 such as at the sealing jaw(s) or the platen surface to provide for either manual or electronic optical inspection. Further, a VIU could be used together with a medical packager to perform both seal integrity tests. The VIU could be an integral part of the MP or the VIU could simply connect to the MP.